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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,792	10/22/2003	Elizabeth A. Recupero	EAR-101A	5621

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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,792

Applicant(s)

RECUPERO, ELIZABETH A.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/22/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 22, 2003 was filed on the mailing date of the Application. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (U.S. Patent No. 5,918,599) in view of Naimer (U.S. Patent No. 6,573,419).

With respect to **Claim 1**: Shesol teaches a tracheostomy tube dressing comprising a) wrap material 12 (top element) having a top surface 18 and bottom surface 20 and being of predetermined shape with a first perimeter distance. Wrap 12 has a central cut out area 26 with a second predetermined distance wherein the first predetermined distance associated with wrap 12 is greater than the second predetermined distance associated with cut out area 26; c) Gauze pad 38 (middle element) has a top and bottom and a predetermined shape wherein its perimeter distance is greater than said second perimeter distance. Pad 38 is located beneath said top element and is attached to the bottom surface 20 of said top element. Pad 38 has a cut out area, wherein the cut out area 26 of said top element is at least partially coincidental, as seen in

With respect to b), Shesol does not teach a clear polymer window. Naimer teaches a self-adhering absorbent dressing material comprised of a transparent material, i.e. clear polyolefin polymer (middle element). This material has a predetermined size, shape and window perimeter distance greater than said second perimeter distance taught by Shesol. Naimer teaches that this transparent material allows observation of continued bleeding, therefore it would be obvious to one of ordinary skill in the art to modify the device of Shesol by adding the transparent material taught by Naimer to allow observation of bleeding by positioning said material beneath the top element where it will be attachable to the bottom of said top element because of its self-adhesive property.

With respect to d), Shesol does not teach a clotting agent attached to the bottom of said middle element and within said cut out of said bottom element 38. Naimer teaches that said transparent middle element contains a coagulant that is applied to the wound by compression of said dressing material, i.e. the coagulant is disposed on the bottom, wound facing surface of said dressing (middle element). Naimer teaches that coagulants enhance wound healing

therefore it would be obvious to one of ordinary skill in the art to use the material taught by Naimer having coagulant disposed on the bottom surface.

With respect to **Claim 2**: Shesol does not teach a clotting agent and therefore does not teach a clotting agent having a gel format. Naimer teaches by reference to U.S. Patent No. 6,045,570 to Epstein et al, a coagulant comprising gelatin, i.e. the coagulant is in gel format. Epstein states that the use of gelatin effectively holds a coagulant in place over a puncture and prevents continued bleeding, therefore it would be obvious to one of ordinary skill in the art to utilize a coagulant in gel format in the device taught by Shesol, as taught by Naimer to ensure secure positioning and effectiveness of the coagulant.

With respect to **Claim 3**: Shesol does not teach that the bottom of pad 38 (bottom element) includes an adhesive, however since the gauze pad engages the surface of the wound, it would be obvious to one of ordinary skill in the art to include adhesive on the bottom of bottom element 38 to further ensure securement in place of said gauze pad in addition to the hook fasteners disposed on the top of bottom element 38.

With respect to **Claim 4**: As can be seen in Fig. 1 taught by Shesol, the perimeter distance of the bottom element 38 is less than the first perimeter distance associated with wrap material 12 (top element).

With respect to **Claim 5**: As can also be seen in Fig. 1 taught by Shesol, bottom element 38 is centrally positioned relative to top element 12 and is shaped to establish a bottom inside frame edge of said bottom of said top element.

With respect to **Claim 6**: Shesol teaches that bottom element 38 is a gauze pad, and gauze is a blood absorbing material.

With respect to **Claim 7**: Shesol teaches hook fasteners 50 disposed on the bottom 20 of top element 12, and therefore does not teach adhesive thereon. Both adhesive and hook fasteners are well-known modes of attachment in the art, therefore it would be obvious to one of ordinary skill in the art to substitute the hook fasteners taught by Shesol with adhesive as both would accomplish the identical function of adhering an item to the bottom of said top element.

With respect to **Claim 8**: Shesol does not teach a clotting agent. Naimer teaches by reference to '570 that the coagulant (clotting agent) is thrombin, wherein the clotting activator is thromboplastin. Naimer teaches that coagulants enhance wound healing therefore it would be obvious to one of ordinary skill in the art to use the material taught by Naimer having coagulant disposed on the bottom surface.

With respect to **Claims 9,10**: Shesol does not teach a clotting agent in a breakable container attached to the bottom of a middle element. Naimer teaches that said transparent middle element contains a coagulant that is applied to the wound by compression of said dressing material, i.e. the coagulant is disposed on the bottom, wound facing surface of said dressing (middle element). The coagulant comprises gelatin thus being in a gel format (e.g. a gel cap-claim 10), forming a container for the coagulant that is breakable and attached to the bottom of said transparent material. Naimer teaches that coagulants enhance wound healing therefore it

would be obvious to one of ordinary skill in the art to use the material taught by Naimer having coagulant disposed on the bottom surface as a middle element in the device taught by Shesol.

With respect to **Claim 11**: Shesol teaches that the bottom element 38 has an opening 48 adapted to at least partially enshroud a tracheostomy tube.

With respect to **Claim 12**: Shesol teaches flange 32 (shroud collar) disposed around tracheostomy tube 34 and attached to gauze pad 38 around opening 48.

With respect to **Claim 13**: Shesol teaches that flange 32 has flange openings 30 for receiving hook fastener strips 28, therefore flange 32 is removable attached to top element 12.

With respect to **Claim 14**: Shesol teaches hook fastener strips for the removable attachment of flange 32 and therefore does not teach an adhesive layer for this purpose. Both adhesive and hook fasteners are well-known modes of attachment in the art, therefore it would be obvious to one of ordinary skill in the art to substitute the hook fasteners taught by Shesol with adhesive as both would accomplish the identical function of adhering an item to the bottom of said top element.

With respect to **Claim 19**: Shesol does not teach a foam material for either top element 12 or bottom element 38. Naimer teaches that the absorbent pad of the wound dressing material is a foamed material. Naimer also teaches that the absorbent material could be woven, as is the material taught for bottom element 38 taught by Shesol. Since Naimer teaches that these

materials are equivalent, it would be obvious to one of ordinary skill in the art to substitute foam as taught by Naimer for gauze as the material for the bottom element as taught by Shesol.

With respect to **Claim 20**: Shesol does not teach a water-impermeable clear polymer window. Naimer teaches a self-adhering absorbent dressing material comprised of a transparent material, i.e. clear polyolefin polymer (middle element). This material has a predetermined size, shape and window perimeter distance greater than said second perimeter distance taught by Shesol. Naimer teaches that this transparent material allows observation of continued bleeding, therefore it would be obvious to one of ordinary skill in the art to modify the device of Shesol by adding the transparent material taught by Naimer to allow observation of bleeding by positioning said material beneath the top element where it will be attachable to the bottom of said top element because of its self-adhesive property.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (U.S. Patent No. 5,918,599) in view of Naimer (U.S. Patent No. 6,573,419), as applied to claims 1-8, 11-16, 19 and 20 above, and further in view of Heinecke et al (U.S. Patent Application Publication No. 2001/0027285).

With respect to **Claims 15, 16**: Neither Shesol nor Naimer teaches a removable sealing strip attached to adhesive on the bottom of said top element. Heinecke teaches an absorbent window dressing having a simple release liner (removable sealing strip) to protect the adhesive surface of the hydrocolloid dressing. Release liners disposed on an adhesive layer to protect the tackiness and prevent contamination are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to include a removable sealing strip attached to the adhesive

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layer on the bottom of the top element or the bottom of the bottom element of the combined teaching of Shesol and Naimer.

With respect to **Claims 17,18**: Neither Shesol nor Naimer teaches a removable sealing strip. Heinecke teaches a "simple release liner" (removable sealing strip), which is known in the art as being a waterproof strip intended to cover and seal any adhesive surface, including the adhesive surface of the bottom of the middle element of the combined teaching of Shesol and Naimer, thus also covering and sealing the coagulant (clotting agent) disposed thereon. Release liners disposed on an adhesive layer to protect the tackiness and prevent contamination are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to include a removable sealing strip attached to the adhesive layer on the bottom of the top element or the bottom of the bottom element of the combined teaching of Shesol and Naimer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

